MAR 1 1 2014

K132322

Section 006 – 510(k) Summary (SMDA Requirements)

Additional Information – October 31, 2013

This Summary of Safety And Effectiveness is submitted in accordance with 21 CFR 807.92.c.

01 – Administrative Information

01- a. Type of 510(k) submission:

These documents constitute a Traditional 510(k) Submission.

01- b. Submission date: July 19, 2013

01-c. 510(k) Submitter:

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01-d. Contact Person:

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01- e. Establishment Registration Number: 8044015

02 – Device Information

02-a. Trade Name of Device:	NEWTRON P5 XS B.LED
02-b. Common Name of Device:	Ultrasonic Scaler
02-c. Classification Regulation:	21 CFR 872.4850
02-d. Medical Device Class:	II
02-e. Panel:	Dental
02-f. Product Code:	ELC

Section 006 – 510(k) Summary (SMDA Requirements)

Additional Information – October 31, 2013

03 – Identification of Legally Marketed Predicate(s)

The Substantial Equivalence (SE) of the Satelec New Device is based on the Predicate Devices identified in the Table 01.

Table 01 – Identification of Legally Marketed Predicate Devices

N°	Trade Name	Manufacturer	Product Code	510(k) number	Date Cleared
1	SUPRASSON P5 NEWTRON	SATELEC	ELC	K050895	April 20, 2005
2	ProUltra Piezo Ultrasonic	SATELEC	ELC	K113430	February 23, 2012
3	PMAX NEWTRON XS	SATELEC	ELC	K071424	August 24, 2007

04 – Description of the Device

The Satelec New Device is a Dental Ultrasonic Generator. The Satelec New Device uses Piezoelectric Technology. The Satelec New Device uses a Satelec Dental Piezoelectric Handpiece (NEWTRON SLIM B.LED).

The Satelec New Device is designed to be used with Satelec Dental Tips previously cleared with Predicate Devices (K050895, cleared April 20, 2005 and K113430, cleared February 23, 2012).

Principles of operation:
An electrical signal emitted by the medical device is supplied to the dental ultrasonic handpiece. This is connected to the medical device via a cord. The handpiece comprises a piezoelectric ceramic transducer, which transforms the electrical signal into ultrasonic vibrations. Mechanical vibrations are transmitted to a tip or a dental file attached to the end of the ultrasonic handpiece.

Scientific principles:
The ultrasonic mechanical vibrations transmitted to the tip or to the dental file attached to the end of the ultrasonic handpiece remove dental plaque and / or dental tartar.

05 – Intended Use

This medical device is intended for prophylaxis, including scaling, for periodontics, for endodontics, and for preservation and restoration dentistry, including prosthesis.

06 – Performance Data

It has been determined in the Section 019 "Performance Testing – Bench" that the Satelec New Device and Predicate Device Satelec SUPRASSON PMAX NEWTRON XS (K071424, cleared August 24, 2007) are similar because the measured values of the Irrigation Flow and the values of the Current delivered in the Piezoelectric Handpiece are similar.

Clinical Data is not needed for this 510(k) process.

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Additional Information – October 31, 2013

07 – Tests and Used Standards

Electromagnetic Compatibility Test:

The Electromagnetic Compatibility Tests have been performed according to IEC 60601-1-2:2007, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests (Edition 3).

Electrical Safety Tests:

The Electrical Safety Tests have been performed according to IEC60601-1:2005, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (General).

Sterilization Validation:

The Sterilizability Tests have been performed according to ISO 17665-1:2006, Sterilization of health care products - Moist heat - Part 1: Requirements for the development, validation, and routine control of a sterilization process for medical devices and ISO 17665-2 : 2009 of Sterilization of health care products - Moist heat - Part 2: Guidance on the application of ISO 17665-1.

08 – Technological characteristics of the Device compared to the Predicate Devices

Technological characteristics of the Satelec New Device are the same as the Predicate Device.

Technological Perspective:

The Satelec New Device and the Predicate Devices use the same technology (Piezoelectricity Technology).

Material perspective:

The Satelec New Device and the Predicate Devices are very similar because the casings are made in self-extinguishing material (UL94V-0).

Design perspective:

The Satelec New Device and the Predicate Devices are very similar because they use:

- The same Principle of User's interface.
- A Piezoelectric Handpiece.

Energy source perspective:

The Satelec New Device and the Predicate Device n°3:

- Use the same input energy source (Electric Mains Power Supply).
- Deliver the same output energy source (ultrasonic micro-vibration).
- Deliver the same Handpiece Current Values.
- Deliver a similar irrigation Flow values for considered clinics.

Light function perspective:
The Satelec New Device and the Predicate Device n°3:

- Use the same principle of LED ring.
- Use the same principle of Optical Guide.
- Use the same quantity of LEDs on the LED ring.
- Use the same reference of LEDs.
- Use the same color of light.

The Light Function does not induce rise temperature on the clinical site.

09 – Determination of substantial equivalence

The Satelec New Device has same Indication Statement as the Predicate Devices Satelec ProUltra Piezo Ultrasonic (K113430, cleared February 23, 2012), Satelec SUPRASSON P5 NEWTRON (K050895, cleared April 20, 2005) and Satelec PMAX NEWTRON XS (K071424, cleared August 24, 2007).
The Satelec New Device is similar in terms of technological characteristics as the Predicate Devices Satelec ProUltra Piezo Ultrasonic (K113430, cleared February 23, 2012), Satelec SUPRASSON P5 NEWTRON (K050895, cleared April 20, 2005) and Satelec PMAX NEWTRON XS (K071424, cleared August 24, 2007).
The Satelec New Device is similar in terms of Performance Data as the Predicate Device Satelec PMAX NEWTRON XS (K071424, cleared August 24, 2007).
The Satelec New Device is similar in terms of Light function as the Predicate Device Satelec PMAX NEWTRON XS (K071424, cleared August 24, 2007).
The identified differences have no impact on the Intended use, Safety and Effectiveness. Effectiveness of the Satelec New Device is the similar as of the Predicate Devices. The Satelec New Device and Predicate Devices are manufactured by SATELEC.

10 – Conclusion

Satelec New Device is Substantially Equivalent (SE) to the Satelec SUPRASSON P5 NEWTRON (K050895, cleared April 20, 2005), Satelec ProUltra Piezo Ultrasonic (K113430, cleared February 23, 2012), and Satelec PMAX NEWTRON XS (K071424, cleared August 24, 2007).

End of Section

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 11, 2014

Satelec-Acteon Group
Mr. Rick Rosati
Quality Manager
124 Gaither Drive, Suite 140
Mt. Laurel, NJ 08054

Re: K132322
Trade/Device Name: NEWTRON P5 EX B.LED
Regulation Number: 21 CFR 872.4850
Regulation Name: Ultrasonic Scaler
Regulatory Class: II
Product Code: ELC
Dated: February 10, 2014
Received: February 11, 2014

Dear Mr. Rosati:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

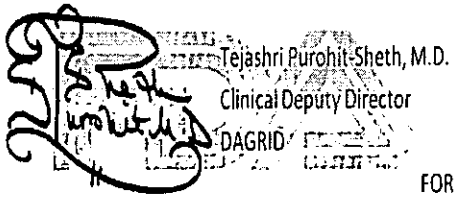
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



FOR

Erin I. Keith, M.S.
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 005 – Indication for Use
Additional Information – October 31, 2013

Indications for Use

510(k) Number (if known): K132322

Device Name: NEWTRON P5 XS B.LED

Indications for Use:

This medical device is intended for prophylaxis, including scaling, for periodontics, for endodontics, and for preservation and restoration dentistry, including prosthesis.

Prescription Use ___X___ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mary S. Runner -S
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